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100 Garden City Plaza, Suite 500 *Records*
Garden City, NY 11530 *Supreme Court*
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CHRISTIE MCDONALD
117 E Main St,
Sherman, MS 38828

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, PA 19454

and

**TEVA WOMEN'S HEALTH, LLC f/k/a TEVA WOMEN'S
HEALTH, INC.**
425 Privet Road
Horsham, PA 19044

and

**DURAMED PHARMACEUTICALS, INC., a division of
Barr Pharmaceuticals, Inc., d/b/a TEVA WOMEN'S
HEALTH, INC.,**
1090 Horsham Road
North Wales, PA 19454

and

**TEVA WOMEN'S HEALTH, INC., individually, and as
successor in interest to, DURAMED
PHARMACEUTICALS, INC., a division of Barr
Pharmaceuticals, Inc.,**
1090 Horsham Road
North Wales, PA 19454

and

**TEVA WOMEN'S HEALTH, LLC., individually and as
successor in interest to TEVA WOMEN'S HEALTH, INC.**
425 Privet Road
Horsham, PA 19044

and

**PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION**

July TERM, 2020

DOCKET NO: # 200701550

Jury Trial Demanded

**Assessment of Damages Hearing is
Required**

**CooperSurgical, Inc.,
95 Corporate Drive
Trumbull, CT 06611**

And

**The Cooper Companies, Inc.,
6140 Stoneridge Mall Rd, Suite 590
Pleasanton, CA 94588**

Defendants.

CIVIL ACTION COMPLAINT/NOTICE TO PLEAD

NOTICE You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER (OR CANNOT AFFORD ONE), GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

**PHILADELPHIA COUNTY BAR
ASSOCIATION LAWYER REFERRAL
AND INFORMATION SERVICE 1101
MARKET STREET, 11TH FLOOR
PHILADELPHIA, PENNSYLVANIA
19107 TELEPHONE: (215) 238-1701**

**THIS OFFICE CAN PROVIDE YOU
WITH INFORMATION ABOUT HIRING
A LAWYER.**

**IF YOU CANNOT AFFORD TO HIRE A
LAWYER, THIS OFFICE MAY BE
ABLE TO PROVIDE YOU WITH
INFORMATION ABOUT AGENCIES
THAT MAY OFFER LEGAL SERVICES
TO ELIGIBLE PERSONS AT A
REDUCED FEE OR NO FEE.**

AVISO Le han demandado en corte. Si usted quiere defenderse contra las demandas nombradas en las páginas siguientes, tiene veinte (20) días a partir de recibir esta demanda notificación para entablar personalmente o por un abogado una comparecencia escrita y también para entablar con la corte en forma escrita sus defensas y objeciones a las demandas contra usted sin previo aviso para conseguir el dinero demandado en el pleito o para conseguir cualquier otra demanda o alivio solicitados por el demandante. Usted puede perder dinero o propiedad u otros derechos importantes para usted.

USTED DEBE LLEVAR ESTE DOCUMENTO A SU ABOGADO INMEDIATAMENTE. SI USTED NO TIENE ABOGADO (O NO TIENE DINERO SUFICIENTE PARA PAGAR A UN ABOGADO) VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA NOMBRADA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL. ESTA OFICINA PUEDE PROPORCIONARLE LA INFORMACION SOBRE CONTRATAR A UN ABOGADO.

ASOCIACION DE LICENCIADOR DE PHILADELPHIA VICIO DE REFERENCIA DE INFORMACION LEGAL 1101 MARKET STREET, 11TH FLOOR PHILADELPHIA, PENNSYLVANIA 19107 TELEFONO: (215) 238-1701

SI USTED NO TIENE DINERO SUFICIENTE PARA PAGAR A UN ABOGADO, ESTA OFICINA PUEDE PROPORCIONAR INFORMACION COBRE AGENCIAS QUE OFRECEN SERVICIOS LEGALES A PERSONAS QUE CUMPLEN CON LOS REQUISITOS PARA UN HONORARIO REDUCIDO O NINGUN HONORARIO.

COMPLAINT

CIVIL ACTION

Plaintiff, Christie McDonald, by and through her undersigned attorneys, files this complaint against Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., d/b/a Teva Women's Health, LLC, Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., f/k/a Teva Women's Health, Inc., Teva Women's Health, LLC, f/k/a Teva Women's Health, Inc., as successor in interest to Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., (collectively referred herein as "Teva Defendants"), and against CooperSurgical, Inc., and the Cooper Companies, Inc., (collectively referred herein as "Cooper Defendants") both jointly and severally, the companies that designed, developed, manufactured, tested, performed safety surveillance, labeled, packaged, distributed, marketed and/or sold the ParaGard Intrauterine medical device ("ParaGard IUD") implanted into Plaintiff throughout the United States. Accordingly, Plaintiff alleges, and states as follows:

INTRODUCTION

1. This is an action for damages relating to the Defendants' design, manufacture, surveillance, sale, marketing, advertising, promotion, labeling, packaging, and distribution of ParaGard Intrauterine medical device (hereinafter "ParaGard IUD").
2. The ParaGard IUD is an intrauterine device, however, it is regulated as a drug. It is placed into the uterus to prevent conception.
3. The ParaGard IUD has a propensity to break at the arms upon explant resulting in serious injuries.
4. Plaintiff used the ParaGard IUD, and as a result of its use suffered injuries.

PARTIES

5. Plaintiff, Christie McDonald is an adult citizen and resident of the state of Mississippi, residing at 117 E Main St, Sherman, MS 38828 who was implanted with Defendants' ParaGard IUD.

6. Defendant Teva Pharmaceuticals USA, Inc. (“Teva Pharmaceuticals” or “Teva USA”) is a corporation with headquarters located at 1090 Horsham Rd. in North Wales, Pennsylvania. At times relevant to this action, Teva USA designed, developed, manufactured and marketed the ParaGard IUD at issue. At times relevant to this action, Teva USA communicated with the United States Department of Health and Human Services, Food and Drug Administration (FDA”) regarding the sale, use, and safety concerns related to ParaGard IUDs, which includes managing product recalls, investigating adverse events from ParaGard IUD users, and performing mandatory reporting to FDA regarding ParaGard.

7. At times relevant to this action, Teva USA was involved in regulatory communications, and medical communications, including but not limited to communications with physicians, doctors and other medical personnel, which led to activities giving rise to failure to warn, negligence, gross negligence, common law fraud, negligent misrepresentation, breach of warranty, and a violation of consumer protection laws.

8. Defendant Teva Women’s Health, Inc., (“Teva Women’s Health”) is a corporation with headquarters located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Defendant Teva USA, and/or operated as a successor-in-interest to Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., and/or assumed Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., in a name change after its acquisition by Teva USA. Teva Women’s Health, Inc., converted into Teva Women’s Health, LLC in 2017 and continues to operate as Teva Women’s Health, LLC. At times relevant to this action, Teva Women’s Health designed, developed, manufactured and marketed the ParaGard IUD at issue.

9. Defendant Teva Women’s Health, LLC is a corporation with headquarters located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Defendants Teva Pharmaceuticals. Teva Women’s Health, LLC is the product of an entity conversion pursuant to Pennsylvania Statute 15 Pa.C.S. §356, and Del. Code Ann. Tit. 8, 266. Teva Women’s Health, Inc., converted into Teva Women’s Health, LLC and continues to operate as a limited liability company instead of an incorporation. Teva Women’s Health, LLC formerly known as Teva Women’s Health, Inc., shall herein be collectively referred to as “Teva Women’s Health”.

10. Accordingly, Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., d/b/a Teva Women's Health Inc., (hereafter referred to as "Duramed"), acquired FEI Women's Health in 2005 wherein the asset of ParaGard was acquired in the deal. Duramed was acquired by Teva USA in 2008 wherein its name was changed to Teva Women's Health, Inc., a wholly-owned subsidiary of Teva USA.

11. At times relevant hereto and alleged herein, the Teva Defendants conducted and continues to regularly conduct substantial business within the Commonwealth of Pennsylvania and within Philadelphia County, which included and continues to include, the research, safety surveillance, manufacture, sale, distribution and marketing of the ParaGard IUD, which is distributed through the stream of interstate commerce into Pennsylvania and Philadelphia County.

12. Defendant The Cooper Companies, Inc., ("Cooper Companies") is a corporation with headquarters at 6140 Stoneridge Mall Rd., in Pleasanton, California. The Cooper Companies purchased assets and global rights and business of the ParaGard IUD in September 2017 for \$1.1 Billion, including their manufacturing facility in Buffalo, New York.

13. Defendant CooperSurgical, Inc., ("Cooper Surgical") is a corporation with headquarters at 95 Corporate Drive in Trumbull, Connecticut and a subsidiary of Defendants The Cooper Companies (collectively Defendants The Cooper Companies and CooperSurgical are referred herein as the "Cooper Defendants").

14. At all times relevant hereto and alleged herein, The Cooper Defendants conducted and continues to conduct substantial business within the State of Pennsylvania.

15. At times relevant hereto, each Defendant acted in all aspects as the agent and alter ego of each other.

16. The Cooper Defendants are liable as successors-in-interest under the Pennsylvania Uniform Voidable Transactions Act, 12 Pa. Stat. and Cons. Stat. Ann. § 5101, *et seq* and the Pennsylvania Fraudulent Transfer Act, 73 Pa. Stat. Ann. § 201-1, *et seq*.

17. Upon reasonable belief, Duramed became Teva Women's Health, Inc., through a name change in 2008. Teva Women's Health, Inc., then became Teva Women's Health, LLC through a conversion in 2017. Teva Women's Health, LLC then sold all of its assets including the

ParaGard to the Cooper Defendants in 2017. Teva Women's Health, LLC became a *holdings* company with no tangible assets.

18. The Cooper Defendants knew or should have known that the transfer and conversion of Teva Women's Health, Inc., was intended to thwart potential creditors from having a claim against Teva Women's Health, Inc or Teva Women's Health, LLC. Therefore, the Cooper Companies are liable pursuant to the Pennsylvania Consumer Protection Acts.

19. The liability of these companies has passed on through various business instruments and now lies with Teva Women's Health, Inc, Teva Pharmaceuticals USA, Inc., the Cooper Companies Inc., and CooperSurgical, Inc.

20. At times relevant and material hereto, Defendants were engaged in the business of, or were successors-in-interest to entities engaged in the business of, researching, developing, designing, formulating, licensing, manufacturing, testing, producing, processing, assembling, packaging, inspecting, distributing, selling, labeling, monitoring, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the Commonwealth of Pennsylvania, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the ParaGard, a drug used in the prevention of pregnancy, implanted in patients throughout the United States, including Plaintiff.

JURISDICTION AND VENUE

21. Plaintiff incorporates by reference all of the above paragraphs.

22. Jurisdiction is proper over the Defendants based upon 42 Pa. C.S.A. 5301.

23. This Court has proper jurisdiction over the Teva Defendants who are citizens and residents of the Commonwealth of Pennsylvania.

24. The Court has personal jurisdiction over the Defendants pursuant to, and consistent with Pennsylvania's long-arm statute (42 Pa.C.S. 5322) and both the Commonwealth of Pennsylvania's and Federal Constitutional requirements of Due Process in so far that Defendants, acting through agents or apparent agents, committed one or more of the following:

- a. Defendants transacted and continue to transact, business in the Commonwealth of Pennsylvania, 42 Pa.C.S. 5322(a)(1), and conducted, and regularly conduct business, receive substantial revenues, and sell and perform services in Philadelphia, Philadelphia County, Pennsylvania;
- b. Defendants have an interest in, uses, or possess real property in the Commonwealth of Pennsylvania, 42 Pa.C.S.5322(a)(5);
- c. Requiring Defendants to litigate this claim in the Commonwealth of Pennsylvania does not offend traditional notions of fair play and substantial justice and is permitted by the U.S. Constitution.

25. Venue is proper in this County pursuant to Pa. R.C.P. No. 2179, which provides, in relevant part, that “a personal action against a corporation or similar entity may be brought in and only in (1) the county where its registered office or principal place of business is located; (2) a county where it regularly conducts business,” because all of the Defendants regularly conduct business in Philadelphia County.

26. Jurisdiction and venue are proper in this Honorable Court, as Teva Defendants have sufficient contacts with the Commonwealth of Pennsylvania, including the City of Philadelphia, through their substantial and purposeful transaction of business here, including but not limited to their receipt of substantial compensation, revenues and/or profits from sales of the ParaGard IUD, as well as, conducting safety surveillance, marketing and/or promotion, storage and delivery of the ParaGard drug and engagement in the strategy and strategic design and implementation of ParaGard for commerce within the Commonwealth of Pennsylvania, all of which led to the causes of actions herein.

27. This is an action for damages, exclusive of interest and costs, which exceeds the sum of fifty thousand dollars (\$50,000).

28. Plaintiff’s claims in the is action are brought solely under state law. Plaintiff does not bring assert or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. 1331.

29. Federal diversity jurisdiction is lacking in this matter as complete diversity does not exist between the parties and therefore the federal courts lack jurisdiction under 28 U.S.C. 1332.

30. Further, at this stage of litigation, a choice of law analysis is not yet ripe for review; Plaintiff reserves her right to pursue the causes of action listed herein based upon the facts pled and discovered.

FACTUAL ALLEGATIONS

31. At relevant times, all Defendants designed, researched, manufactured, labeled, packaged, promoted, marketed and/or sold the ParaGard IUD at issue after receiving New Drug Application approval from FDA.

32. ParaGard is an intrauterine drug that can provide long term birth control, up to 10 years, without hormones.

33. The ParaGard drug is a T-shaped plastic frame made of polyethylene and barium sulfate that is inserted into the uterus. Copper wire coiled around the IUD produces an inflammatory reaction that is toxic to sperm and egg. A monofilament polyethylene thread is tied through the tip, resulting in two white threads, which aid in the detection and removal of the drug.

34. The ParaGard IUD has a propensity to break at the arms upon explant resulting in serious injuries.

35. In 2008, Teva USA became the owner of ParaGard when it acquired Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., through its purchase of Barr Pharmaceuticals.

36. Upon information and belief, when Teva USA acquired Duramed, a division of Barr Pharmaceuticals, Inc., it also acquired Duramed's manufacturing facilities, sales force and responsibility for maintaining and updating the labeling for ParaGard.

37. Shortly thereafter, Teva USA changed the name of Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., to Teva Women's Health, Inc., a wholly owned subsidiary of Teva USA.

38. Upon information and belief, Teva Women's Health, Inc., is simply a new name for Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc.

39. Upon information and belief, and for purposes of liability and interest, Teva Women's Health, Inc., is the same entity as Teva Women's Health, LLC. Teva Women's Health, Inc., converted into Teva Women's Health, LLC under the laws of Delaware. Del. Code Ann. Tit. 8, 266. Pursuant to Del. Code Ann. Tit. 8, 266, a company that converts from one entity into another is deemed to be a continuation of the preexisting company. A conversion does not equate to a dissolution and no winding up takes place. Therefore, Teva Women's Health, Inc., did not dissolve, windup, or *cease to exist* and liability continues from the corporation to the Limited Liability Company.

40. Upon information and belief on August 11, 2017, Teva Women's Health, Inc., converted into Teva Women's Health, LLC and sold off all of its assets.

41. On September 11, 2017, Teva Defendants sold the ParaGard to Cooper Defendants.

42. ParaGard is currently sold only in the U.S. and had earned revenues of approximately \$168 million for the twelve-month period ending June 30, 2017.

43. At times relevant, Teva and Cooper Defendants engaged in extensive mass media direct-to-consumer advertising of ParaGard for the purpose of increasing sales.

44. The ParaGard was marketed heavily by Teva and Cooper Defendants as being safe and effective, and promising fewer side effects than other birth control methods.

45. The marketing and promotional efforts of Teva and Cooper Defendants, their advertisers, and sales force served to overstate the benefits of ParaGard and minimize and downplay

the risks. These promotional efforts were made while Teva Defendants fraudulently withheld important safety information from health care providers and the public.

46. The Cooper Defendants still manufacture and sell the ParaGard in the U.S.

47. Prior to Plaintiff being implanted with the ParaGard IUD, Defendants knew and should have known that the drug was defective and unreasonably dangerous.

48. Teva and Cooper Defendants knew or should have known that ParaGard can and does cause serious harm to individuals who use it, due to the risk of the ParaGard's arm breaking upon removal.

49. Teva and Cooper Defendants knew of these risks from the trials they performed, their post-marketing experience and complaints, third party studies, and their own analysis of these studies, but took no action to adequately warn or remedy the defects and instead concealed, suppressed and failed to disclose or fix this danger.

50. The product warnings for ParaGard were vague, incomplete or otherwise wholly inadequate to alert prescribing physicians and patients to the actual risks associated with ParaGard.

51. Teva and Cooper Defendants' marketing and promotion, through its own website, sought to reassure physicians and patients that Defendants' longstanding record of quality and safety assurance.

52. Based upon these representations, upon which Plaintiff and her physician relied, Plaintiff had the ParaGard implanted, believing it would be safe and effective, for the entire duration it was implanted and upon removal.

53. Since 2010, the FDA has received over 1600 reports of ParaGard breakage, with over 700 classified as serious.

54. Defendants failure to adequately communicate and report to the FDA the injuries associated with ParaGard resulted in inadequate warnings.

FACTUAL BACKGROUND

55. On information and belief, in September 25, 2009, Plaintiff was implanted with Defendants' ParaGard IUD by a physician.

56. Plaintiff, a young and healthy woman, wanted a ParaGard because it was a reversible form of birth control that would allow her to conceive in the future.

57. In July 25, 2018, Plaintiff went to have the ParaGard IUD removed in Sanders Clinic for Women by Johnny F. Miles, MD.

58. Johnny F. Miles, MD attempted to remove the ParaGard as instructed by Teva, by grasping the ParaGard by the forceps and pulling gently. Despite following the instructions provided by Defendants only a portion of the ParaGard was retrieved while a ParaGard arm was retained. Johnny F. Miles, MD proceeded to confirm the location of the retained ParaGard IUD arm via ultrasound in order to schedule a diagnostic hysteroscopy.

59. In August 7, 2018, Johnny F. Miles, MD attempted to remove the retained ParaGard IUD arm via hysteroscopy at North Mississippi Medical Center without success.

60. Prior to her procedures, Plaintiff and her doctors were provided with no warning from the Defendants of the risk of ParaGard failure and injury, nor were Plaintiff and her doctors provided with adequate warning of the risk of removal of ParaGard. This information was known or knowable to the Defendants.

61. As a direct result of Plaintiff's use of the ParaGard, Plaintiff suffered from having a broken arm of the ParaGard in her, causing her damage, including but not limited to pain, suffering, mental anguish, the loss of reproductive health, loss of enjoyment of life, medical expenses and other out of pocket losses and loss of income.

DISCOVERY RULE, ESTOPPEL, AND FRAUDULENT CONCEALMENT

62. Plaintiff incorporates by reference the factual portion of this Complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, allege as follows.

63. Plaintiff plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortuous nature of the wrongdoing that caused the injury.

64. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relation to the Plaintiff's ParaGard IUD and Defendants' wrongful conduct was not discovered and could not have been discovered, until a date within the applicable statute of limitations for filing each of Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

65. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's filing of their causes of action.

66. The Defendants' fraudulent concealment did result in such delay. Defendants' are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of their ParaGard IUD.

COUNT I – NEGLIGENCE

67. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

68. At times relevant, Teva Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling and/or distributing the ParaGard IUD, including the one that was implanted into the Plaintiff.

69. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, safety surveillance and distribution of the ParaGard so as to avoid exposing others to foreseeable and unreasonable risks of harm.

70. Defendants breached their duty of care to the Plaintiff and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, safety surveillance, and distribution of the ParaGard.

71. Defendants knew or reasonably should have known that the ParaGard IUD was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

72. At the time of the manufacture and sale of the ParaGard IUD, Defendants knew or should have known that the ParaGard IUD was designed and manufactured in such a manner so as to present an unreasonable risk of the fracture of the arm of the drug upon removal.

73. At the time of the manufacturer and sale of the ParaGard IUD, Defendants knew or should have known that the ParaGard IUD was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement and subsequent removal.

74. At the time of the manufacture and sale of the ParaGard IUD, Defendants knew or should have known that using the ParaGard IUD for its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe injuries, including but not limited to additional surgeries and/or medical procedures in order to remove the fragmented drug, even leading to hysterectomy.

75. Defendants knew or reasonably should have known that the consumers of the ParaGard IUD would not realize the danger associated with using the drug for its intended use and/or in a reasonably foreseeable manner.

76. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the ParaGard IUD in, among others, the following ways:

- a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;
- b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other drug available for the same purpose;
- c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;
- d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare providers or the general health care community about the ParaGard IUD's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;
- e. Failing to perform reasonable pre-and post-market testing of the ParaGard IUD to determine whether or not the product was safe for its intended use;
- f. Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the ParaGard IUD;
- g. Advertising, marketing and recommending the use of the ParaGard IUD, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the ParaGard IUD;
- h. Representing that the ParaGard IUD was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

- i. Continuing manufacture and sale of the ParaGard IUD with the knowledge that the IUD was dangerous and not reasonably safe, and failing to comply with the FDA good manufacturing regulations;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the ParaGard IUD so as to avoid the risk of serious harm associated with the use of the IUD;
- k. Failing to establish an adequate quality assurance program used in the manufacturing of the ParaGard IUD; and
- l. Failing to establish and maintain an adequate post-marketing surveillance program for the ParaGard IUD.
- m. Failing to adequately and correctly report safety information relative to the ParaGard product resulting in inadequate warnings.

77. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

78. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

79. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II – STRICT LIABILITY DESIGN DEFECT

80. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

81. The ParaGard is inherently dangerous and defective, unfit and unsafe for its intended use and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

82. The ParaGard IUD was expected to, and did, reach its intended consumer without substantial change in the condition in which it was in when it left Defendants' possession.

83. The ParaGard IUD implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the products would have expected at time of use.

84. The ParaGard IUD implanted in Plaintiff was defective in design, in that the IUD's risks of harm exceeded its claimed benefits.

85. Plaintiff and her healthcare providers used the ParaGard IUD in a manner that was reasonably foreseeable to the Defendants.

86. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered the IUD's defective conditions or perceived its unreasonable dangers prior to her implantation of the drug.

87. As a result of the foregoing design defects, the ParaGard created risks to the health and safety of its users that were far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the ParaGard.

88. Defendants have intentionally and recklessly designed the ParaGard with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

89. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

90. As a proximate result of the Defendants' design of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in

excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT III – STRICT LIABILITY MANUFACTURING DEFECT

91. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

92. Teva Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, performed pharmacovigilance, distributed and sold the ParaGard IUD that was implanted into the Plaintiff.

93. The ParaGard IUD implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time the ParaGard IUD left Defendants' control and possession.

94. Plaintiff and Plaintiffs' health care providers used the drug in a manner consistent with and reasonably foreseeable to Defendants.

95. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.

96. The ParaGard was defectively and/or improperly manufactured, rendering it defective and unreasonably dangerous and hazardous to Plaintiff.

97. As a result of the manufacturing defects, the ParaGard creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the ParaGard.

98. Defendants have intentionally and recklessly manufactured the ParaGard with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

99. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

100. As a proximate result of the Defendants' manufacture of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT IV – STRICT LIABILITY FAILURE TO WARN

101. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

102. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the ParaGard IUD, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the drug to consumers or persons responsible for consumers.

103. At the time Defendants designed set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the ParaGard IUD into the stream of commerce, Defendants knew or should have known that the drug presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

104. Specifically, Defendants knew or should have known that the ParaGard IUD posed a significant risk that one of the arms of the drug could break upon removal, resulting in significant injuries.

105. Defendants had a duty to warn of the risk of harm associated with the use of the drug and to provide adequate warnings concerning the risk the drug could break upon removal, even if implanted properly and even if the drug remained properly in-place.

106. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the ParaGard, and the complete lack of a safe, effective procedure for removal of the ParaGard.

107. The risks associated with the ParaGard IUD are of such a nature that health care providers and users could not have recognized the potential harm.

108. The ParaGard IUD was defective and unreasonably dangerous at the time of its release into the stream of commerce due to the inadequate warnings, labeling and/or instructions accompanying the product, including but not limited to, the implantation and subsequent removal of ParaGard.

109. The ParaGard IUD, when implanted in Plaintiff, was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Defendants.

110. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

111. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

112. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT V – COMMON LAW FRAUD

113. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

114. The Defendants have falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that the ParaGard IUD had been appropriately tested and was found to be safe and effective.

115. The representations made by the Defendants were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the ParaGard.

116. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase the ParaGard for use as a form of long-term birth control, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

117. In representations to Plaintiff and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted the following material information:

- n. That the ParaGard was not as safe as other products and procedures available to aid in the long-term prevention of pregnancy;
- o. That the risk of adverse events with the ParaGard was higher than with other products and procedures available for birth control;
- p. The ParaGard IUD was not adequately tested;
- q. That the limited clinical testing for ParaGard revealed a higher risk of adverse events, above and beyond those associated with other products and procedures available for birth control;
- r. That Defendants deliberately failed to follow up on the adverse results from clinical studies and/or formal and informal reports from physicians and/or other healthcare providers and either ignored, concealed and/or misrepresented those findings;

- s. That Defendants were aware of dangers in the ParaGard IUD in addition to and above and beyond those associated with other products and procedures available for birth control;
- t. That the ParaGard IUD was defective, and that it caused dangerous and adverse side effects, including but not limited to unacceptable incidence of breakage upon removal;
- u. That when the ParaGard IUD needed to be removed, the removal procedure had a very high failure rate and/or needed to be performed repeatedly;
- v. That the ParaGard IUD was manufactured negligently;
- w. That the ParaGard IUD was manufactured defectively; and
- x. That the ParaGard IUD was designed negligently and designed defectively.

118. The Defendants were under a duty to disclose to Plaintiff and her physicians, the defective nature of the ParaGard, including but not limited to, the risk of breakage prior to and upon removal, which could result in permanent injury.

119. The Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the ParaGard, such as Plaintiff.

120. The Defendants' concealment and omissions of material facts concerning the safety of the ParaGard IUD were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or dispense the ParaGard IUD; and/or to mislead them into reliance upon and cause them to use the ParaGard IUD.

121. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians, used the ParaGard IUD, Plaintiff and/or her physicians were unaware of the falsehood of these representations, and reasonably believed them to be true.

122. The Defendants knew and had reason to know that the ParaGard IUD could and would cause severe and grievous personal injury to the users of the product and was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

123. In reliance upon these false representations, Plaintiff and her physicians were induced to, and did use the ParaGard IUD, thereby causing severe and permanent personal injuries and damages to Plaintiff. The Defendants knew or had reason to know that the Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the ParaGard IUD, as described in detail herein.

124. Plaintiff and her physicians reasonably relied on facts provided by the Defendants which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent to the use of the ParaGard IUD.

125. Having knowledge based on the Defendants research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the ParaGard IUD was safe for use as a means of providing long-term birth control and was as safe or safer than other product and/or procedures available and/or on the market. As a result of Defendants' research and testing, or lack thereof, these Defendants intentionally omitted, concealed and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff, her physicians, and the public at large.

126. The Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

127. The information distributed to the public, the medical community, Plaintiff and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of the ParaGard IUD.

128. These representations, and others made by the Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

129. The Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the ParaGard to Plaintiff, her physicians and the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

130. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the ParaGard.

131. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of the Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when the ParaGard IUD was surgically implanted into her.

132. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the ParaGard IUD, neither Plaintiff nor her physician would not have purchased, used, or relied on Defendants' representations and omissions concerning the ParaGard IUD.

133. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

134. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been seriously injured, and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT VI – NEGLIGENT MISREPRESENTATION

135. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

136. At relevant times, Teva Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning the ParaGard IUD, including, but not limited to, misrepresentations regarding the safety of the ParaGard IUD.

137. The information distributed by the Defendant to the public, the medical community, the Plaintiff and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of the ParaGard IUD.

138. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' health care providers; to falsely assure them of the quality of the ParaGard IUD and the induce the public and medical community, including Plaintiff and her healthcare provider to request, recommend, prescribe, implant, purchase and continue to use the ParaGard IUD.

139. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical drug manufacturers, Plaintiff, her healthcare providers and the public, that the ParaGard IUD had been tested and found to be safe and effective for long term birth control.

140. The representations made by the Defendants were, in fact, false. The ParaGard IUD was not safe for human use in its intended and reasonably foreseeable manner. Use of the ParaGard IUD is dangerous as there is a risk that it may fracture upon removal cause significant injury.

141. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use the ParaGard IUD, thereby causing Plaintiff to endure severe and permanent injuries.

142. Defendants knew and had reason to know that the Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

143. Plaintiff and her healthcare providers would not have recommended, and implanted ParaGard IUD had the true facts not been concealed by the Defendants.

144. Defendants had sole access to the material facts concerning the defective nature of the ParaGard IUD and its propensity to cause serious and dangerous side injuries.

145. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff was implanted with the ParaGard IUD, Plaintiff and her healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

146. The Defendants failed to exercise ordinary care in making representations concerning the ParaGard IUD while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the ParaGard's high risk of unreasonable and dangerous adverse side effects.

147. The Defendants breached their duty to Plaintiff, her physicians, and the medical and healthcare community, by representing that the ParaGard IUD has no serious side effects different from older generations of similar products or procedures.

148. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendants, where they concealed and misrepresented facts that were critical to understanding the true dangers inherent in the use of the ParaGard IUD.

149. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

150. The Defendants knew, and had reason to know, that the ParaGard had been insufficiently tested, or had not been tested at all, that the products lacked adequate and accurate warnings, that they created a high risk, and/or higher than acceptable risk, and/or higher than reported risk that they represented a risk of adverse side effects, including, pain and suffering, surgery to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

151. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

152. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT VII – BREACH OF EXPRESS WARRANTY

153. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

154. At relevant times, Teva Defendants intended that the ParaGard be used in the manner that Plaintiff used it and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for long-term birth control, and that they were adequately tested and fit for their intended use.

155. At relevant times, Teva Defendants were aware that consumers, including Plaintiff, would use the ParaGard; which is to say that Plaintiff was a foreseeable user of the ParaGard.

156. Plaintiff and/or her implanting physicians were, at all relevant times, in privity with the Defendants.

157. ParaGard was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by the Defendants.

158. The Defendants breached various express warranties with respect to the ParaGard including the following particulars:

- y. The Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the ParaGard was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the ParaGard;
- z. The Defendants represented to Plaintiff and her physicians and healthcare providers that the ParaGard was as safe, and/or safer than other alternative procedures and drugs and fraudulently concealed information, which demonstrated that the ParaGard was not safer than alternatives available on the market; and
- aa. The Defendants represented to Plaintiff and her physicians and healthcare providers that the ParaGard was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the products.

159. In reliance upon the Defendants' express warranties, Plaintiff was implanted with the ParaGard as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

160. At the time of making such express warranties, the Defendants knew or should have known that the ParaGard does not conform to these express representations because the ParaGard was not safe and had numerous side effects, many of which the Defendants did not accurately warn about, thus making the ParaGard unreasonably unsafe for its intended purpose.

161. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of the Defendants in connection with use, recommendation, description, and/or dispensing of the ParaGard.

162. The Defendants breached their express warranties to Plaintiff in that the ParaGard was not of merchantable quality, safe and/or fit for its intended uses, nor was it adequately tested.

163. The Defendants' breach constituted violations of common law principles and 13 Pa. Stat. Ann. §2313, *et seq.*

164. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

165. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT VIII – BREACH OF IMPLIED WARRANTY

166. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

167. At relevant and material times, Teva Defendants manufactured, distributed, advertised, promoted, and sold the ParaGard.

168. At relevant times, Teva Defendants intended that the ParaGard be implanted for the purposes, and in the manner, that Plaintiff or her physicians or surgeons used it and the Defendants impliedly warranted each ParaGard to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

169. Defendants were aware that consumers, including Plaintiff or her physicians or surgeons would implant the ParaGard in the manner described by the instructions for use and that Plaintiff was the foreseeable user of the ParaGard.

170. Plaintiff and/or her physicians and surgeons were at all relevant times in privity with Defendants.

171. The Defendants' ParaGard was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians and surgeons, without substantial change in the condition in which they manufactured and sold by Defendants.

172. Defendants breached various implied warranties with respect to the ParaGard, including the following particulars:

- bb. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical literature, and regulatory submissions that the ParaGard was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the ParaGard;
- cc. Defendants represented that the ParaGard was safe, and/or safer than other alternative drugs or procedures and fraudulently concealed information, which demonstrated that the ParaGard was not as safe or safer than alternatives available on the market; and
- dd. Defendants represented that the ParaGard was more efficacious than other alternative treatments and fraudulently concealed information, regarding the true efficacy of the ParaGard.

173. In reliance upon Defendants' implied warranties, Plaintiff and/or her implanting physicians and surgeons used the ParaGard as prescribed in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

174. Defendants breached their implied warranties to Plaintiff and/or her implanting physicians and surgeons in that the ParaGard was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles and the following statutory provision: 13 Pa. Stat. Ann. §§2314 *et seq.*

175. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

176. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT IX – VIOLATION OF CONSUMER PROTECTION LAWS

177. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

178. Plaintiff purchased and used the ParaGard primarily for personal use thereby suffering ascertainable losses, as a result of the Defendants' actions in violation of the consumer protection laws.

179. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for the ParaGard and would not have incurred related medical costs and injury.

180. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the ParaGard, that was implanted into her, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

181. Unfair methods of competition of deceptive acts or practices that were proscribed by law, including the following:

- ee. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;
- ff. Advertising goods or services with the intent not to sell them as advertised; and
- gg. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

182. Plaintiff was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including the Plaintiff and her physicians, was to create demand for and promote the sale of ParaGard. Each aspect of the Defendants' conduct combined to artificially create sales of the ParaGard.

183. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the ParaGard.

184. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the ParaGard and would not have incurred related medical costs.

185. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq.*

186. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq.*

187. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute(s) listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

188. Teva and Cooper Defendants engaged in fraudulent behavior regarding the transfer and/or sale of assets to Cooper Defendants in 2017. Cooper Defendants knew or should have reasonably known that the transfer of assets was done in a manner consistent with and in an effort to, deceive potential creditors.

189. Pursuant to the terms of the asset purchase agreement, Teva Women's Health, Inc., claims to maintain liability for all ParaGard placed prior to the execution of the asset purchase agreement in September of 2017. However, Teva Women's Health, Inc., converted to Teva Women's Health, LLC and sold off all of its assets.

190. Cooper Defendants knew or reasonably should have known that Teva Defendants converted Teva Women's Health, Inc., into Teva Women's Health, LLC after selling off or moving all assets from Teva Women's Health, Inc.

191. Therefore, Cooper Defendants knew or reasonably should have known that Teva Defendants shuffling of assets and subsequent conversions were done to thwart potential creditors in violation of state and Federal consumer protection laws.

192. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the ParaGard was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

193. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

194. The Defendants had actual knowledge of the defective and dangerous condition of the ParaGard and failed to take any action to cure such defective and dangerous conditions.

195. Plaintiff and her implanting physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

196. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

197. By reason of the unlawful acts engaged by the Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

198. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

199. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT X – GROSS NEGLIGENCE

200. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

201. The wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants, knowing that they were false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

202. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

203. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

204. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused that

injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct, and which would deter other manufacturers from engaging in such misconduct in the future.

205. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$50,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT XI – PUNITIVE DAMAGES

206. Plaintiff incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

207. At times material hereto, Teva Defendants knew or should have known that their ParaGard, as designed, manufactured, assembled, sold and/or distributed was inherently dangerous.

208. At times material hereto, Teva Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their ParaGard.

209. Teva Defendants' misrepresentations included knowingly withholding material information from the public and consumers alike, including Plaintiff, concerning the safety of the ParaGard.

210. At times material hereto, Teva Defendants knew and recklessly disregarded the fact that their ParaGard could cause serious, disabling, and permanent injuries to individuals such as Plaintiff.

211. Notwithstanding the foregoing, Teva Defendants continued to aggressively market and promote their ParaGard IUD, without disclosing the risks.

212. As a direct and proximate result of Teva Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, endured pain and

suffering, and has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

213. Teva Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Teva Defendants and deter them from similar conduct in the future.

214. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common and statutory law.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

- (a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
- (b) For medical, incidental, and hospital expenses according to proof;
- (c) For pre-judgment and post-judgment interest as provided by law;
- (d) For compensatory damages in excess of the jurisdictional minimum of this Court;
- (e) For consequential damages in excess of the jurisdictional minimum of this Court;
- (f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
- (g) For attorneys' fees, expenses, and costs of this action; and
- (h) For such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,

Pogust Millrood, LLC

Dated: September 23, 2020

By: /s/ Tobias Millrood

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